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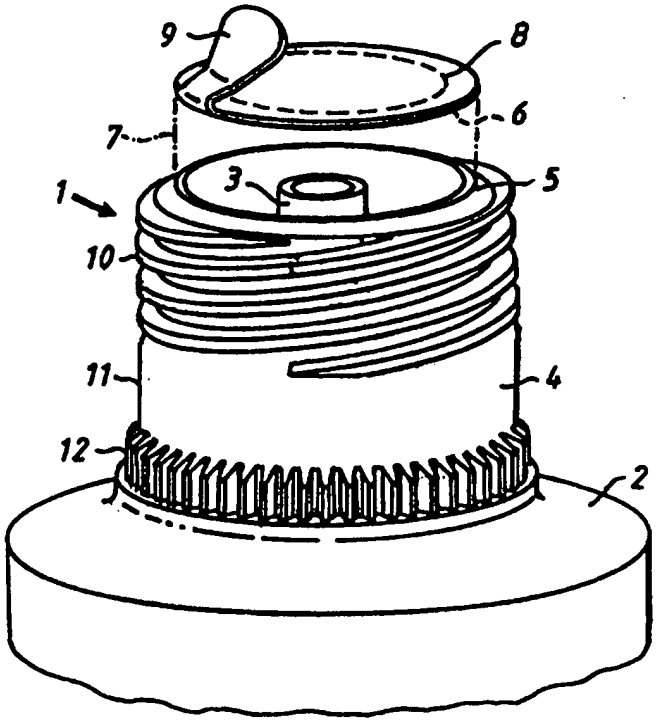
(54) Title: DOUBLE SEAL CAP

(57) Abstract

A double seal cap for protecting connection ports of a medical device, such as a dialyzer. The cap has screw threads (21) for cooperation with screw threads (10) of the port. A sealing portion (22) of the cap, in the form of a ridge portion (24), cooperates with a substantially cylindrical sealing surface (11) of the port to form a first seal. The upper portion of the cap is covered by a membrane (25) permeable to a sterilization agent (ETO or steam) and forming a second seal. Integrity means (27) at the bottom portion of the cap indicate if the cap has been tampered during transportation or storage.



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DOUBLE SEAL CAP

AREA OF INVENTION

The present invention relates to a double seal cap for a medical device, especially for a dialyzer, for protecting connection ports or other connections of the device from contamination after a sterilization process.

PRIOR ART

After the manufacturing of a dialyzer, a blood line system or other similar medical device, the dialyzer is packed in a protective wrapping, such as a plastic bag and/or a paper wrapping, and the entire pack is exposed to a sterilization agent, such as ethylene oxide (ETO), steam, plasma sterilisation or similar. After the sterilization procedure, the product is stored, transported and subsequently used, whereby the protective wrapping is removed before use. An undamaged wrapping indicates that the sterility of the product is maintained from manufacturing to the time of use.

The connection ports are already provided with an inner seal or sterility barrier, which forms a barrier against microbiological contamination. The inner seal is usually attached directly to the connection port of the dialyzer.

DISCLOSURE OF THE INVENTION

The object of the present invention is to provide an alternative for the commonly used wrapping, which is more easily recycled and means a cut down on material expenditure. Especially the volume of the waste wrapping material is reduced by a factor of 10 or more.

According to the present invention, it is noted that a major portion of the dialyzer does not need any protection, such as the outer peripheral surface. It is only the connection ports and the surrounding area which actually need protection against contamination.

Thus, according to the invention, a double seal cap is provided, which is intended to be placed on the connection ports or similar area to be protected of a dialyzers, blood line systems or similar medical devices.

The double seal cap according to the invention has the features defined in the following claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is described in more details below with reference to the embodiments shown on the appended drawings in which:

Fig. 1 is a perspective view of a connection port at the blood side of a dialyzer to be provided with an inner seal and adapted to be provided with a cap according to the invention.

Fig. 2 is a cross-sectional view of a double seal cap according to the invention intended to be placed on the port shown in Fig. 1.

Fig. 3 is a partially cut perspective view of the cap shown in Fig. 2.

Fig. 4 is a perspective view of the cap shown in Fig. 3 with a tongue in an opened position.

Fig. 5 is a partially cut perspective view of an alternative cap adapted on a corresponding connection port.

Fig. 6 is a partially cut perspective view of another alternative cap.

Fig. 7 is a partially cut perspective view of another cap design according to the invention comprising a bellow portion.

Fig. 8 is a cross-sectional view of another embodiment of the invention.

Fig. 9 is a perspective view of a port design mating to the cap shown in Fig. 8.

Fig. 10 is a partially cut perspective view of another cap and port design according to the invention and adapted for the dialysate solution side of a dialyzer.

Fig. 11 is a partially cut perspective view of still another embodiment of the cap according to the invention, adapted for a dialysate connector.

Fig. 12 is a partially cut perspective view of a port provided with another inner seal and a cap according to the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Fig. 1 is a perspective view of a connection port 1 arranged in the end portion of a dialyzer 2, such as one of two blood connection ports. The dialyzer is also provided with two connection ports for dialysate solution, usually at the side surface of the dialyzer, and the invention is applicable also for said dialysate ports.

The dialyzer housing can be made of different materials such as PC, SAN, ABS, PP, PE or other plastics material.

The port shown in Fig. 1 is provided with an inner luer male connector 3 intended for connection with a blood line to be attached to the dialyzer. The connector is surrounded by a sleeve 4, which is provided with interior threads for interaction with a female luer connector of the blood line, which is provided with outside threads. The outer surface of said sleeve 4 is provided with some formations specific for the present invention, while the outer surface of the sleeve normally is smooth, i.e. without any formations.

The height of the sleeve is the same or slightly higher than the inner male luer connector 3, so that the sleeve exposes a rim portion 5. An inner seal film 6 is attached to said rim portion 5, as shown by arrows 7 in Fig. 1. The seal film 6 is attached to the rim portion by gluing, ultrasonic welding, heat sealing or another technique resulting in a connection which can garantee sterility after termination of the sterilization process.

The inner seal film is made of a membrane material, such as GORETEX®, sterile paper, TYVEK®, (spunbonded olefin from DuPont) etc. or another appropriate membrane material, which is permeable to the sterilization agent used, such as ETO or steam etc.

In order to obtain a good connection between the inner seal film and the housing material (examples mentioned above), a ring portion 8 of the seal film can be coated with a different compatible material, such as a thermosensitive glue. However, at least the inner surface area of the seal film 6 must be permeable to the sterilization agent so that it can penetrate the inner portion of the device.

Other types of sealing film materials can also be used, provided it can be fixed to the sleeve rim portion 5 and still be permeable to the sterilizing agent. One such material is a film provided with several, equally spaced dots of glue material so that the glue spots form a continuous seal at the rim portion but leave free the surface for passage of the sterilizing agent.

Furthermore, the connection between the port material and the inner seal film must be performed in a way that the seal film can be peeled off before use. For this purpose, the seal film is provided with a tear tab 9 as shown.

In other embodiments, the inner seal film can be replaced by screw caps interacting with the inner screw threads of the sleeve and providing a sterile inner protection for the luer connector, compare below in connection with Fig. 12.

For a dialyzer, it is not sufficient to have an inner seal film as described above, but usually the dialyzer is placed in a plastic wrapping providing a contamination barrier or outer seal.

According to the present invention there is instead provided a double seal cap as the outer seal, which basically has three functions:

1) It forms a contamination barrier or outer seal.

2) It is designed so that it protects the sealing materials of the inner and the outer seals from mechanical damage.

3) It should have a built-in control of integrity, which can be mechanical or optical or of other types.

Typical materials for the double seal cap are PE, PP, ABS etc.

A first embodiment of the double seal cap according to the invention is shown in Fig. 2. The cap has generally a complementary shape to the outer surface of the port sleeve 4 shown in Fig. 1. The outer sleeve surface is provided with a screw threaded portion 10, a sealing surface 11 and an indentation portion 12. Similarly, the cap 20 is provided with a screw threaded portion 21 having inner threads, a sealing portion 22 having a sealing ridge 24 and a teeth portion 23. Said sealing ridge 24 forms together with the sealing surface 11 a first seal of the cap.

Additionally, the cap is provided with a sterility membrane 25 attached to the upper end of the cap and forming a second seal of the cap.

The cap 20 is intended to be placed upon the connection port 1 so that the threads 10 and 21 interact to keep the cap in place upon the port. The sealing ridge 24 has an internal diameter, which is slightly smaller than the outer diameter of the sealing surface 11 so that a hermetic seal is formed upon placement of the cap on the port sleeve. The sealing surface 11 is preferably cylindrical but can also be slightly conical so that the seal is safely obtained and the material in the ridge is slightly deformed upon securing the cap on the sleeve.

The teeth portion 23 has one internal tooth 26 (or several teeth) for interaction with serration and indentations in the indentation portion 12 of the sleeve. When the cap has been secured to the sleeve, the tooth 26 prevents unintentional or accidental withdrawal of the cap.

As shown in Figs. 2 and 3, the tooth 26 is provided on a tongue 27 being attached to the teeth portion 23 by two bridge portions 28, forming a hinge, and a breakable portion 29. When the cap should be removed, the breakable portion 29 is ruptured by hand force and the tongue 27 is withdrawn as shown in Fig. 4, whereupon the cap can be removed. Preferably, the tongue is provided with a handgrip 30, shown by dotted lines in Fig. 3 for facilitating the intentional removal of the tongue 27.

The teeth portion 23 ends with a rim portion 31, which interacts with the upper surface of the dialyzer 2 to form an end position for the cap when tightened to the port. Alternatively, such end position can be defined by a shoulder portion 32 above the screw portion 21, which cooperates with the rim portion 5 of the sleeve and the inner seal film 6, 8 attached to said rim portion 5.

Moreover, the cap is provided with a dome portion 33, extending the cap above the rim portion 5 of the sleeve. The dome portion 33 comprises a seal membrane 25 attached inside the dome and covering the upper portion of the cap 20. The dome portion is provided with an inner annular surface 34 forming a connection surface for the seal membrane 25. The seal membrane is at least at the central portion thereof made of a material which is permeable for the sterilization agent used. A suitable material is paper, TYVEK® etc. The seal membrane 25 is fixed inside the dome portion 33 at the annular surface 34 by gluing, ultrasonic welding, heat sealing etc.

The seal membrane 25 is placed at a distance above the tear off seal film 6, so that there is no contact between the two sealing materials.

The seal membrane 25 is connected to the outside of the cap via several slits 35 covered by a cap top 36 as is clearly shown in Fig. 3. Thus, a sterilizing agent such as steam or ETO can enter the cap through said slits 35 and pass the membrane 25 and the film 6 and enter the inside of the medical device for sterilizing purpose. Seal membrane 25 prevents bacteria and other contaminating particles from entering inside the cap via said slits 35. Sealing ridge 24 prevents bacteria and particles from entering the interior of the cap from the other end of the cap, i.e. via the exterior surface of the sleeve. Thus, cap 20 provides a sealed area between ridge 24 and seal membrane 25, which is free from contamination from the outside. Tongue 27 forms an integrity indication means informing the user that the cap has not been tampered during the storage and transport time between the manufacturing and the final use.

When using the double seal cap according to the invention, the tongue is removed as shown in Fig. 4 and the cap is taken off. Then, the seal film 6 is peeled off by means of the tear tab 9, and the dialyzer is ready for use and connection to a blood tube. The protective cap can be collected and returned to the manufacturer for reuse. The only packaging material to be discarded is the material in the tear off seal film 6.

The outer surface of the sleeve has a certain design in order to adapt the sleeve to use according to the present invention and as shown in Fig. 1. In Fig. 5 there is shown another design of the outer surface of the sleeve which can be used according to the present invention.

The sleeve 40 according to Fig. 5 is provided with a generally cylindrical surface having a downwards facing shoulder 42. The double seal cap according to this embodiment lacks the screw thread portion and is provided with a break-off ring portion 43 engaging below said shoulder 42. The break-off ring portion 43 is connected to the remaining cap by a peripheral web portion 44. When the cap should be removed, the break-off ring portion 43 is severed from the cap by pulling a tear tab 45, whereby the web portion 44 breaks around the periphery and frees the remaining cap. The cap is provided with a ridge portion 46 which cooperates with surface 41 of the sleeve to form a contamination seal as in the embodiment shown in Fig. 2. In all other respects, the operation is similar to the embodiment shown in Fig. 2.

Fig. 6 shows another alternative method of attaching the double seal cap to the dialyzer 2. The cap is fixed by means of a "drop" 47 of sealing wax or a glued paper seal. This seal must be destroyed in order to remove the cap, which forms the integrity control. This double seal cap can be used on an ordinary dialyzer without requiring any modification of the outer surface of the sleeve of the dialyzer port.

Sometimes it is desired to have the upper portion of the cap resilient so that it can have a high shock absorbing capacity or accommodate different internal structures. Such an embodiment is shown in Fig. 7. The dome portion is provided with a bellow portion 48 being resilient both in the axial direction as well as in the side direction. In this embodiment, the inner seal film is well protected.

In another alternative embodiment of the double seal cap according to the invention, the threaded portion 21 and the sealing portion 22 are interchanged with each other as shown in Fig. 8. The outer surface of the sleeve is correspondingly shaped as shown in Fig. 9. In this embodiment, the distance between the inner seal film 6 and the outer seal membrane 25 is made larger. Moreover, the sealing surface 50 of the sleeve is provided with a conical portion 51 for interaction with the internal sealing ridge 52 of the cap.

Fig. 10 shows an embodiment of the double seal cap according to the invention adapted to be used on a dialyzer port intended for dialysate solution provided on the side surface of a cylindrical hollow fiber dialysator. The design and operation is very similar to the embodiment shown in Figs. 8 and 9, but the threaded portion is longer and adapted to the screw threads often found on such ports. At the bottom, closest to the dialyzer housing, the port outer surface is provided with several teeth 54, 55, two of which are shown in Fig. 10. Such teeth interact with several teeth 56, 57 on the interior surface of the cap at a tear off band 58 attached to the cap via a rupturable web 58. The operation of this embodiment should be obvious to the reader.

In the embodiment shown in Fig. 11, the cap according to the invention is provided with a snapp fastener ring 59 which engages below a shoulder 60 of the sleeve outer surface 61. When the cap is screwed off the sleeve, a weakened rib 62 breaks between the fastener ring 59 and the remaining cap and forms an integrity indication. In all other respects the embodiment of Fig. 11 corresponds to the embodiment of Fig. 10.

Finally, Fig. 12 shows an embodiment of the cap according to the invention, and substantially as shown in Fig. 8, attached to a sleeve port provided with a removeable inner seal member 63. Said member 63 includes an outer thread 64, engaging an inner thread 65 of the sleeve normally used by the Luer connector of the blood line to be connected to the port. The seal member 63 is provided with a sealing film 66 at its top, permitting passage of the sterilizing agent.

Hereinabove, several embodiments of the double seal cap and the corresponding port have been described with reference to the drawings. It is realized that the different features of the invention shown on the drawings can be combined to further different combinations, which should be obvious to the skilled reader. The double seal cap can also be used on different medical devices where a double seal cap is needed. The invention is only limited by the appended patent claims.

PATENT CLAIMS

1. A cap for protecting a connection port of a medical device, such as a dialyzer, said port being provided with an inner seal, such as a tear off film (6) or a screw member 63, **characterized** by

a connection means (21,43,47,53) for attaching the cap to said port;

a sealing portion (22,24,46,52) for sealing against a portion of said port;

a sealing membrane (25) attached to the cap and being permeable to a sterilizing agent for allowing said agent to enter the interior of the cap.

2. A cap according to claim 1, **characterized** by

an integrity means (27,43,47,58) preventing the removal of the cap from the port without a visual indication.

3. A cap according to claim 1 or 2, **characterized** in that the port comprises

a connection member (10,42) for attaching the cap to said port; and

a sealing member (11,50,51) for sealing against the cap sealing portion.

4. A cap according to claim 3, **characterized** in that said connection means (21,43,47,53) and said connection member (10,42) are mutually cooperating screw threads and that said sealing portion (22,24,46,52) and said sealing member (11,50,51) are a ridge portion at the cap and a cooperating substantially cylindrical surface at the outer surface of the port.

5. A cap according to claim 2, 3 or 4, **characterized** in that said integrity means is an indentation portion (12) of the port and at least one tooth (26) of the cap.

6. A cap according to any one of the previous claims, **characterized** in that said sealing membrane (25) is attached to an upper portion of the cap and is connected to the outside of the cap via slits (35) provided in the upper surface of the cap.

Fig. 2

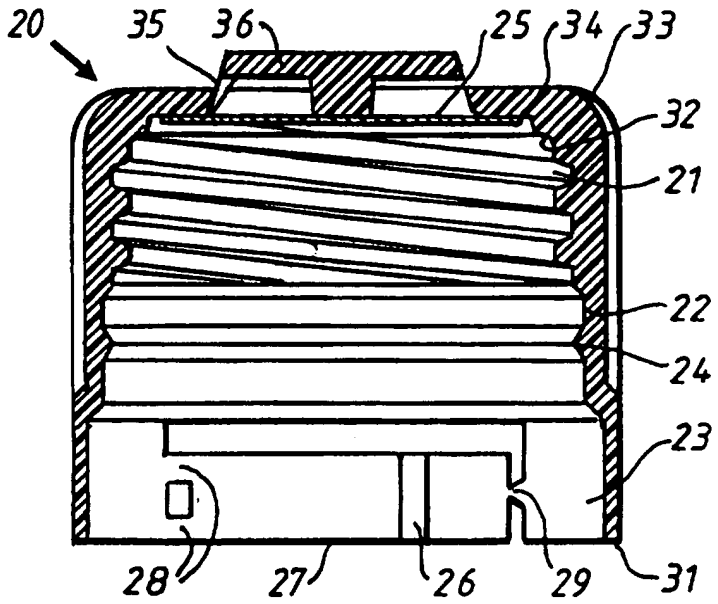


Fig. 1

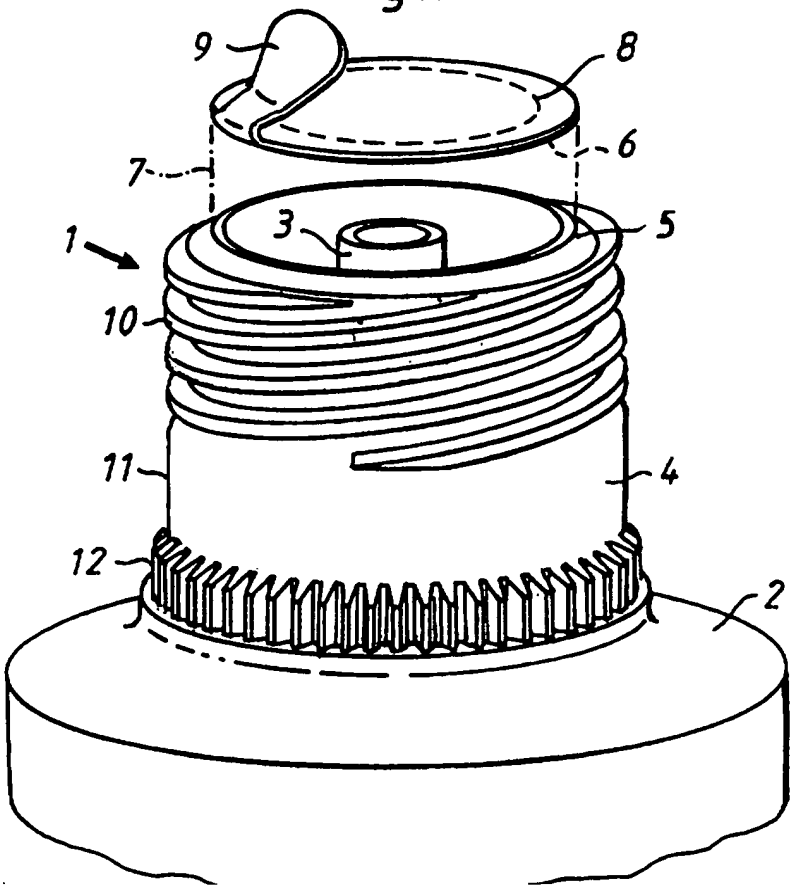


Fig 3

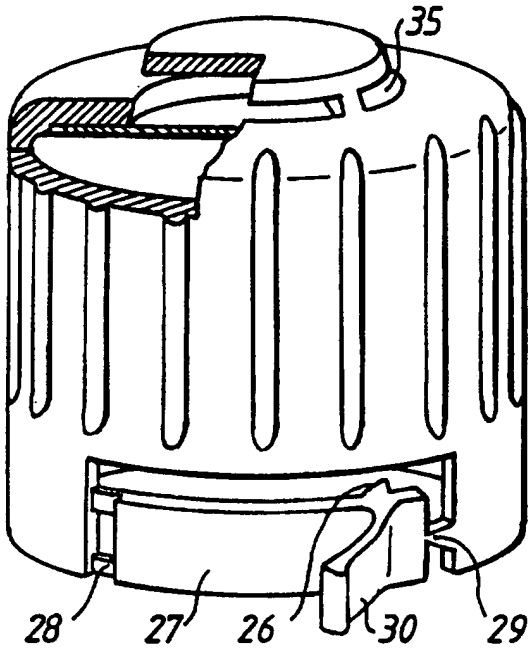


Fig. 4

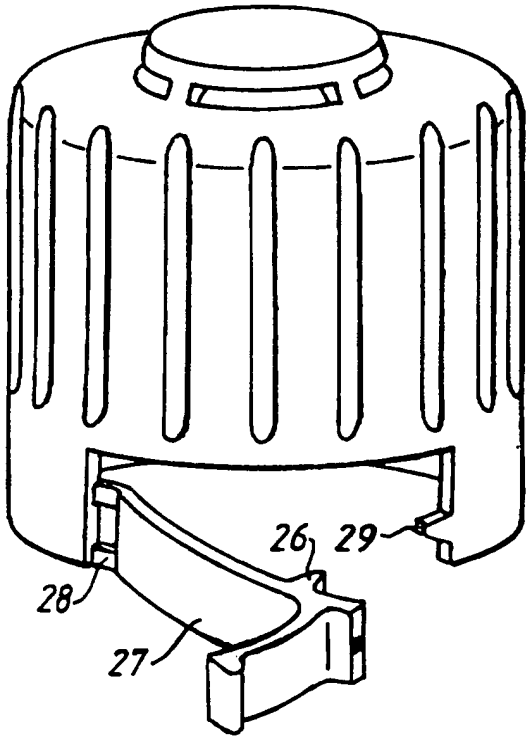


Fig. 5

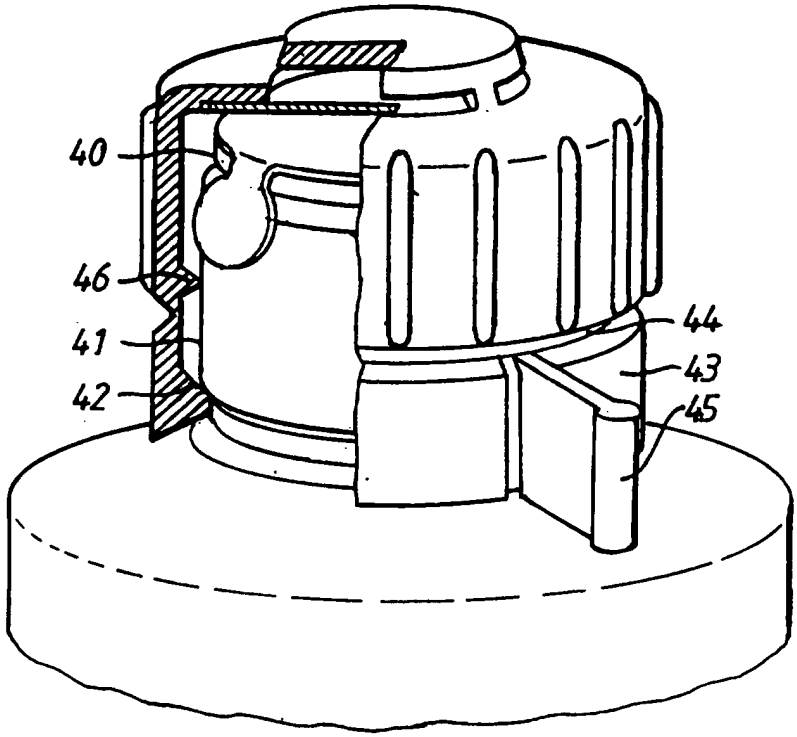


Fig. 6

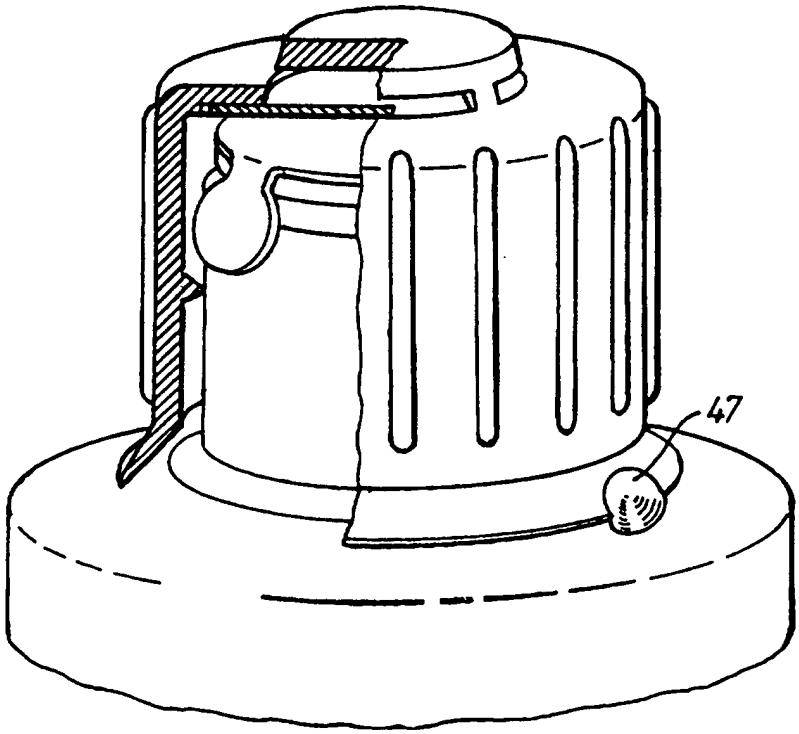


Fig.7

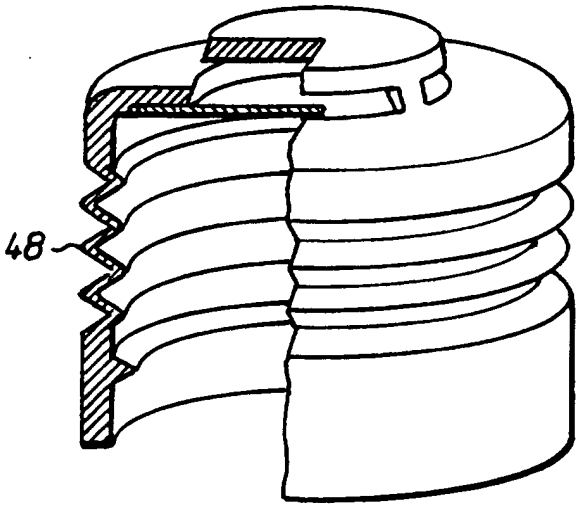


Fig.8

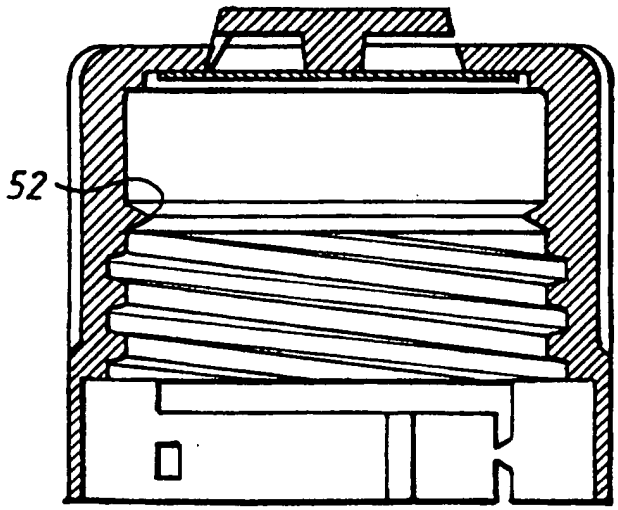


Fig. 9

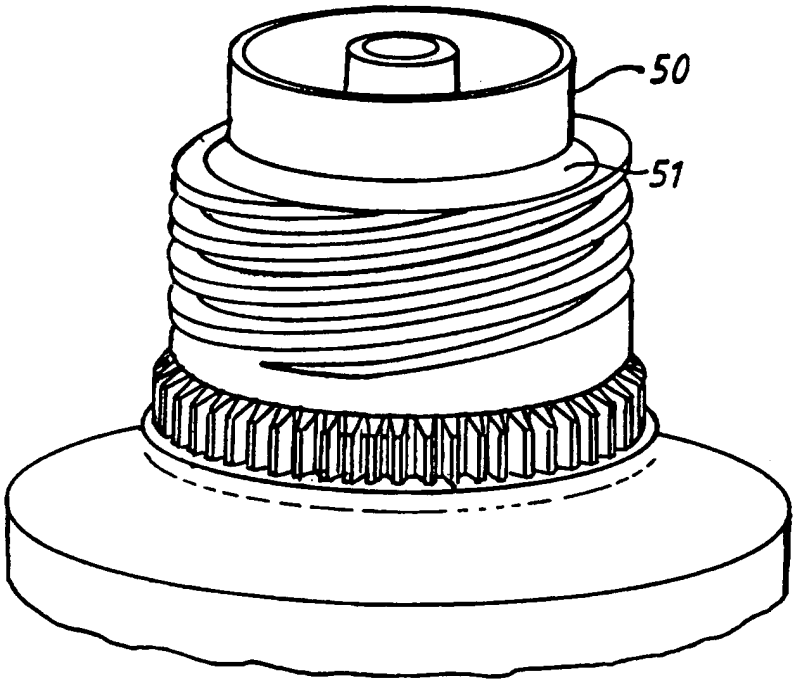


Fig. 10

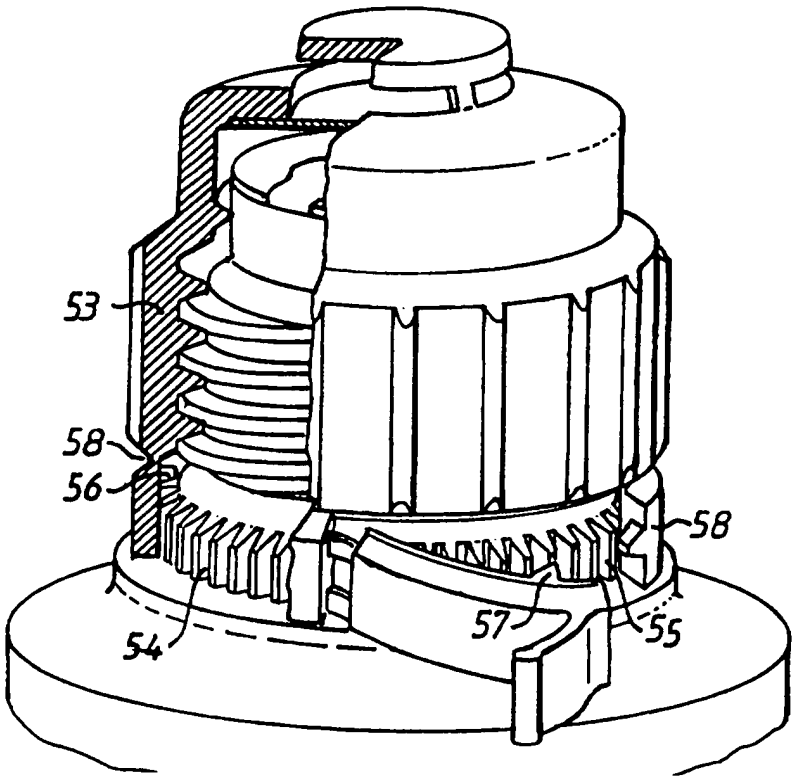


Fig.11

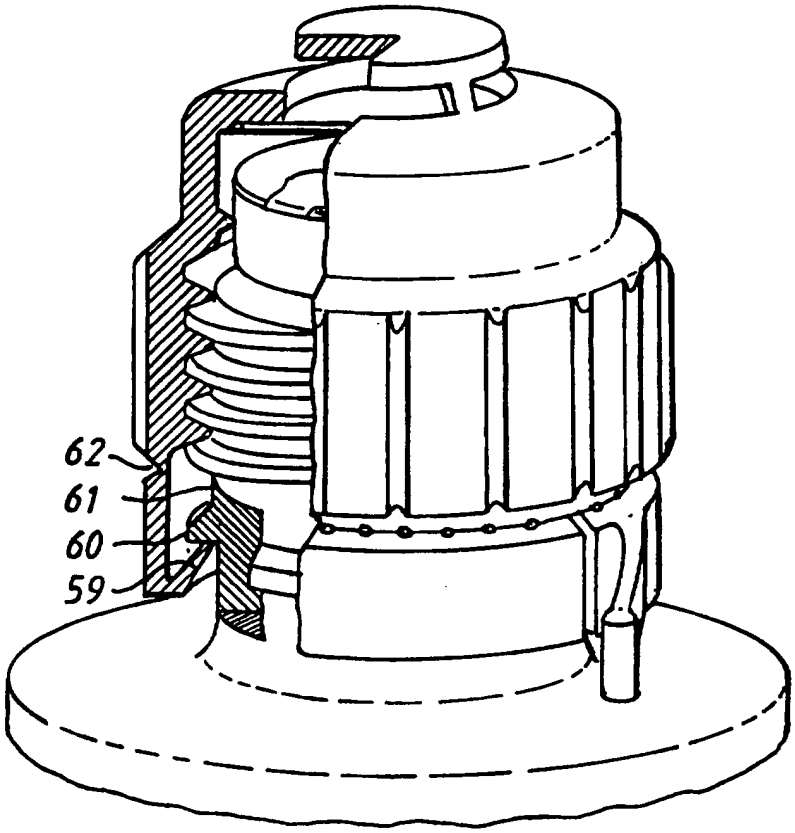
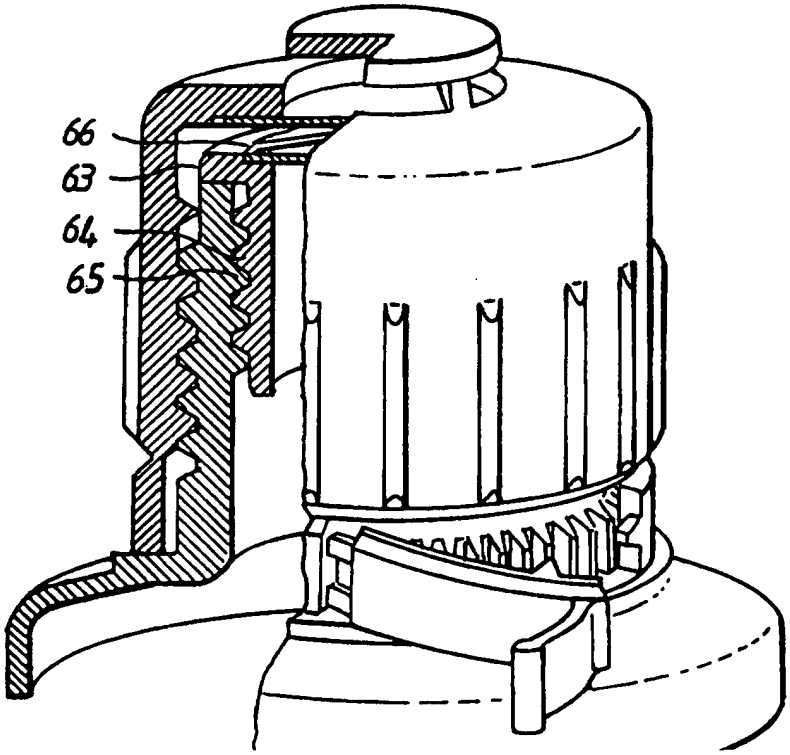


Fig.12



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 97/00095

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 39/20, A61M 1/14
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 9428855 A1 (BAXTER INERNATIONAL INC.), 22 December 1994 (22.12.94), page 10, line 22 - page 11, line 15 --	1-6
Y	US 3923179 A (P.V.CHOKSI ET AL), 2 December 1975 (02.12.75), column 2, line 35 - column 3, line 5 --	1-6

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
6 May 1997	08 -05- 1997
Name and mailing address of the ISA/	Authorized officer

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/04/97

International application No.
PCT/SE 97/00095

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9428855 A1	22/12/94	AU 7059194 A	03/01/95
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US 3923179 A	02/12/75	US 3960002 A	01/06/76